

NOVEL™ VBR Spinal System
510(k) SUMMARY
August 2004

K042201

- I. **Company:** Alphatec Manufacturing, Inc.
6110 Corte Del Cedro
Carlsbad, CA 92009, USA
(760) 431-9286
- OCT 7 - 2004
- II. **Contact Person:** Ellen Yarnall, Director of Regulatory Affairs
- III. **Trade/Proprietary Name:** NOVEL™ VBR Spinal System
- IV. **Classification:** MQP (888.3060) Vertebral Body Replacement Device

V. **Product Description:**

The NOVEL™ VBR Spinal System is a vertebral body replacement device that is implanted into the vertebral body space to improve stability of the spine. System components are offered in three footprints of varying lengths, widths and heights to meet individual patient anatomy. System components are manufactured from titanium alloy (ASTM F136).

VI. **Intended Use:**

The Novel™ VBR Spinal System is intended for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Novel™ VBR Spinal System is intended for use with supplemental spinal fixation systems. Specifically, the Novel™ VBR Spinal System is to be used with the Alphatec Zodiac™ Polyaxial Pedicle Screw System or the Alphatec Mirage™ Top Tightening Spinal System. Additionally, the Novel™ VBR Spinal System is intended for use with bone graft.

VII. **Substantial Equivalence:**

The NOVEL™ VBR Spinal System is substantially equivalent to the following predicate devices

<u>Trade/Proprietary Name</u>	<u>Manufacturer</u>	<u>Clearance</u>
Verte-Stack Spinal System	Medtronic Sofamor Danek	K021791
DePuy AcroMed Stackable Cage	DePuy AcroMed	K990148

VIII. **Performance Data:**

Static and dynamic testing of the NOVEL™ VBR Spinal System was performed. The test results demonstrated that the NOVEL™ VBR Spinal System is at least comparable to, if not better than, those of the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 7 - 2004

Ellen A. Yarnall
Director of Regulatory Affairs
Alphatec Manufacturing, Inc.
6110 Corte Del Cedro
Carlsbad, California 92009

Re: K042201
Trade/Device Name: NOVEL™ VBR Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: August 12, 2004
Received: August 13, 2004

Dear Ms. Yarnall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

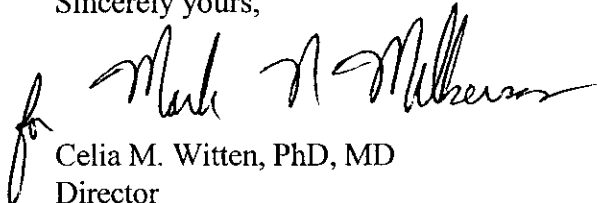
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042201

Device Name: NOVEL™ VBR Spinal System

Indications for Use:

The Novel™ VBR Spinal System is intended for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Novel™ VBR System is intended for use with supplemental spinal fixation systems. Specifically, the Novel™ VBR System is to be used with the Alphatec Zodiac™ Polyaxial Pedicle Screw System or the Alphatec Mirage™ Top Tightening Spinal System. Furthermore, the Novel™ VBR System is intended for use with bone graft.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Miller
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K042201